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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,499	05/04/2001	Herman Waldmann	1324.028	8699

7590                    11/18/2004

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[REDACTED] EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/849,499	WALDMANN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 03 May 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 64, 68-95, 105-108, 110 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 64, 68-95, 105-108, 110 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

Applicants' Request For Continued Examination (RCE) filed 5/3/04 and Amendment has been entered. Claims 65-67 have been cancelled by the amendment filed 5/3/04, claims 110 has been added, however, there is no claim 111 as indicated in Applicants' Response (p. 3). Claim 64 has been amended. Claims 64, 68-95, 105-108 and 110 are pending and under current examination.

### *Objections*

Note: The claims listing, filed on 9/29/04 is *objected* to as being improper for the following reasons:

1. The claim listing is improper because the claims have been given the wrong status identifier. Claims 96-104 and 109 were cancelled in the Amendment, filed 2/12/03 (see p. 6, Remarks Section, 1<sup>st</sup> ¶).

Appropriate correction is required.

### *Specification*

The prior objection to the specification is maintained. Applicants have submitted a replacement specification that comprises the text of the parent published PCT reformatted in accordance with current USPTO practice. However, the substitute specification filed 2/12/03 has not been entered because it does not conform to 37 CFR 1.125(b) because: Applicants have not provided a copy of the

specification excluding the claims, as well as a marked up version of the specification showing all the changes (including the matter being added to and the matter being deleted from) to the specification of record. See also MPEP §608.01(q).

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of claims 64, 68-95, 105-108 and 110 is *maintained* under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing a long-term culture of immature dendritic cells wherein the method comprises culturing ES cells from the mouse embryonic stem cell line ESF116 in the presence of murine IL-3 [and optionally, murine GM-CSF] to bring about differentiation of the ES cells into immature dendritic cells and stimulating the maturation of the immature dendritic cells with LPS, does not reasonably provide enablement for methods for producing long-term cultures of immature dendritic cells utilizing any population of ES cells, for the breadth claimed, culturing the ES cells in the presence of any cytokine or combination of cytokines to bring about the differentiation of the ES cells into immature dendritic cells to produce a long-term culture of immature dendritic cells, and stimulating the mature of the immature dendritic cells with any inflammatory mediator. The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants argue that at least three mice strains were effective in maturing into dendritic cells, namely ESF116, ESF99, and ESF75 and point to the specification for this support. See p. 3 of the Response.

Applicants point to p. 8, lines 19-31 to support this argument. It is noted that the passage is found on page 10, ¶ 44. This is not found to be persuasive because it is unclear what condition(s) these ES cells (ESF99 and ESF74) were cultured in. The specification provides no specific teachings with regard to the generation of immature dendritic cells from these ES cells, other than that they supported development. The specification clearly teaches that the culturing of mouse ES cells to produce DCs is unpredictable, stating, for example, “[C]ertain mouse strains have been found to be permissive for DC development, while ES cells from other strains have not.” Thus, it is maintained that the specification fails to provide an enabling disclosure with regard to any population of ES cells, and the directed differentiation of those ES cells into dendritic cells, as instantly claimed.

Applicants argue that one of skill in the art would enable the claimed invention without undue experimentation to any embryonic stem cell population, namely ES cells from additional mice strains, as well as mammals, including human. (Emphasis added, see p. 4, 1<sup>st</sup> ¶ of the Response). This is not persuasive

because the specification fails to provide an enabling disclosure for utilizing any other ES cell line other than the ESF116 cell line, for the breadth claimed, to produce long-term cultures of immature dendritic cells. In fact, the specification supports that it would be unpredictable to utilize other ES cell lines [see p. 8, lines 19-28] in the claimed methods. Applicants have provided no teachings, guidance or evidence of record to overcome such unpredictability.

Accordingly, in view of the quantity of experimentation necessary for the production of long-term cultures of immature dendritic cells by culturing any ES cells with any cytokine [or combination thereof], the lack of guidance, teachings and examples provided by the specification for the production of long-term cultures of immature dendritic cells from any ES cells with any cytokine, other than the exemplified ESF116 murine ES cell line with IL-3 [and optionally murine GM-CSF], as well as the unpredictable state of the art with regard to the availability of ES cells lines capable of supporting DC development, and the requirement for IL-3 for differentiation, it would have required undue experimentation for one skilled in the art to make and/or use the claimed long-term cultures of dendritic cells and methods of making the same.

*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

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